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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,216	06/13/2001	Robert E. Richard	12013/59001	4088

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EXAMINER

MICHENER, JENNIFER KOLB

ART UNIT	PAPER NUMBER
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1762

DATE MAILED: 03/17/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/879,216

Applicant(s)

RICHARD, ROBERT E.

Examiner

Jennifer Kolb Michener

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-- Th MAILING DATE of this communication appears on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 16-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. This application contains claims 16-20 drawn to a nonelected invention in Paper No. 6. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

2. The rejection of claims 5 and 7 under 35 U.S.C. 112, second paragraph, has been withdrawn.

As necessitated by Applicant's amendments, the following new rejections are made:

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 and 12 have been amended to require coating a "non-polymeric" medical device. This appears to be new matter. Examiner cannot find such a limitation in the originally-filed disclosure. While many of the device examples on page 9 of the

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specification may be made from non-polymers, for example stents may be made of metals, there does not appear to be basis in the originally filed disclosure for claiming all non-polymers.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims have been amended to require coating a non-polymeric substrate.

Claim 11, however, claims that the medical device substrate is chosen from a stent, various catheters, a filter, and a coil. It is not clear to Examiner that all of these substrates may be non-polymeric.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. In light of Applicant's amendment, the rejection of claims 1 and 4-6 under 35 U.S.C. 102(b) as being anticipated by Greiner (EP 0 405 284 A2) has necessarily been withdrawn.

As necessitated by Applicant's amendments, the following new rejection is made:

9. Claims 1-2, 4-8, 10-12, and 14-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Mehta et al. (US 2002/0051845 A1).

Mehta teaches coating a non-polymeric medical device, namely a metallic stent, with therapeutic agents using supercritical fluids (abstract; page 4, P 40). Mehta interfaces a therapeutic with a supercritical solvent and transfers the therapeutic from the supercritical fluid to the medical device (paragraphs 7-9).

The therapeutic agent of Mehta may be applied with a polymer as well, which acts as a carrier, as required by claims 2 and 8. Alternatively, Mehta teaches the addition of a carrier (P 45).

Regarding claim 4, requiring a "bath" of supercritical fluid, Mehta teaches introducing the supercritical fluid into a pressure chamber for suspending the coating materials (P 51). A chamber filled with the fluid to surround the medical device qualifies as a "bath" of said material.

Regarding claims 5 and 6, the therapeutic agent may be dissolved in the supercritical solvent to form a true solution or may be in a suspension of particles (P46).

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Regarding claim 7, Mehta teaches applying supercritical conditions to the coating chamber followed by a controlled restoration to subcritical conditions, thus requiring a vacuum force.

The supercritical fluid of Mehta is carbon dioxide and the therapeutic agent may be paclitaxel (first line of page 5), as is required by claim 10.

While Mehta is primarily concerned with coating stents, he also envisions coating catheters by his method, both of which are required in claim 11 (P 40-41).

Regarding claim 12, Mehta teaches applying a polymer layer prior to the supercritical coating steps of the therapeutic agent (P 34), thus exposing the coating to the supercritical fluid.

As outlined in paragraph 8, the therapeutic agent is interfaced with the supercritical fluid before flooding the coating chamber with the therapeutic-containing supercritical fluid, as is required by claim 14.

The first coating will inherently swell, when contacted with the supercritical fluid, as required by claim 15. Because Mehta meets all of the limitations required by Applicant, the same swelling will inherently occur. If Mehta's outcome was different than Applicant's it must be due to some process limitation not present in Applicant's claims.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. In light of Applicant's amendment, the rejection of claims 3, 7, 9, and 11 under 35 U.S.C. 103(a) as being unpatentable over Greiner has necessarily been withdrawn.

12. In light of Applicant's amendments, the rejection of claim 10 under 35 U.S.C. 103(a) as being unpatentable over Greiner in view of Hossainy (US 6,153,252) necessarily has been withdrawn.

13. In light of Applicant's amendments, the rejection of claims 2, 8, and 12-15 under 35 U.S.C. 103(a) as being unpatentable over Greiner in view of Cook et al. (US 5,916,585) necessarily has been withdrawn.

As necessitated by Applicant's amendments, the following new rejection is made:

14. Claims 3, 7, 9, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehta.

Mehta teaches that which is disclosed above.

Specifically, Mehta teaches flooding the pressurizable coating chamber with supercritical fluid by "introducing" the supercritical fluid into said chamber. Mehta does not specifically teach "spraying" the supercritical fluid into the chamber, however, it appears to Examiner that pumping/spraying or pouring would be the most practical ways to deliver a supercritical fluid.

Additionally, Mehta teaches spraying and dipping as well-known coating mechanisms (p. 1, P 3).

Therefore, it would have been obvious to one of ordinary skill in the art to select spraying as a suitable means to "introduce" a supercritical fluid to the pressure chamber of Mehta in light of Mehta's disclosure of these methods for delivering coatings to medical devices.

Regarding claims 7 and 9, Mehta teaches recycling of the supercritical carbon dioxide solvent (P 18), but fails to specifically teach recycling of the therapeutic agent.

Examiner notes that Mehta's method of flooding a stent with a solution of a therapeutic agent will not result in attachment of all therapeutic agent that is present in solution to the surface of the stent. After coating, excess supercritical fluid, with therapeutic agent dissolved therein, is taught by Mehta to be recycled. Due to the high expense of pharmaceutical products, it is Examiner's position that one of ordinary skill in the art would recycle the excess therapeutic agent, along with the carbon dioxide, to recover such expensive agents for a subsequent coating operation. In recovering the solution from the coating chamber, a pump would be required to move the solution. Creating a pressure differential, using a vacuum, would have been obvious to one of ordinary skill in the art desiring to move the solution from the chamber to a recycling location.

Respons to Arguments

15. Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kolb Michener whose telephone number is 703-306-5462. The examiner can normally be reached on Monday through Thursday and alternate Fridays.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 703-308-2333. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



Jennifer Kolb Michener
March 5, 2003


FRED J. PARKER
PRIMARY EXAMINER